

## REMARKS

In the Office Action dated March 15, 2006, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following two separate and distinct inventions:

- Group I.        Claims 1-13, drawn to a method for the treatment of infections by treating patients with a composition comprising phospholipase, classified in class 435, subclass 183.
- Group II.       Claims 14-21, drawn to a composition comprising phospholipase and a carrier, classified in class 424, subclass 94.1.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group II, Claims 14-21, drawn to a composition comprising phospholipase and a carrier, classified in class 424, subclass 94.1. Applicants reserve the right to file a divisional application directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present

application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Specifically, the Examiner acknowledges that Groups I and II are related as product and process of use. However, relying on MPEP § 806.05(h), the Examiner contends that Groups I and II are distinct inventions, allegedly because the product of Group II can be used in a process materially different from that of Group I, such as in a method for producing enzyme-modified lecithin.

Applicants respectfully submit that Groups I and II are merely different aspects of a single invention. The methods of Group I teach how to make and use the product of Group II. Applicants further submit that the interdependence of Groups I-II is confirmed --indeed, it is mandated-- by virtue of the fact that 35 U.S.C. § 112 compels disclosure of all aspects of the invention in the one application which applicants have filed. For example, an application claiming a product comprising phospholipase is required to disclose inter alia how to make and use that invention. In other words, a description of the means and method for using the subject product is a mandatory part of the application to the product itself. Indeed, if any of these aspects of a complete disclosure were omitted, the application could be considered defective under §112, first paragraph. Consequently, it is clear that aspects of a given invention, such as a product, its use, and the process of producing that product, are necessarily interdependent, not independent, from each other.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the

manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q.

2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of the two groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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